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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 41

Application Number: 08/813,950
Filing Date: March 03, 1997
Appellants: ASSMUS ET AL.

Samuel H. Blech
For Appellants

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed November 23, 1999.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 17-24 stand or fall together because the brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,708,874	De Haan et al.	11/1987
5,552,159	Mueller et al.	9/1996
204,596	Europe (Yves et al.)	12/1986

(10) Ground of Rejection

The following ground of rejection are applicable to the appealed claims. The text of section 103 of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Haan et al, Mueller et al and European Patent No. 204,596.

De Haan et al (col. 7, Example 1) shows a pharmaceutical active substance (i.e. theophylline) coated and bound with 83% by weight of an acrylic plastic (Eudragit RSPM, deemed a suitable species according to page 11, lines 3-8 of the specification) and 17% by weight of cetyl alcohol (designated as an operable flow improver on page 14, line 6 of the specification).

Mueller et al (col. 3, lines 9-20) a pharmaceutical active substance, a polymeric binder such as Eudragit RS (col. 4, lines 13-16), hydroxyalkylcellulose and polyethylene glycol (col. 3, line 3; a species of flow improver defined in claim 22, lines 4-5) prepared by melt-mixing at a temperature of from 60-150°C and cooling to solidification.

The European patent (page 11, Table II, Example 17) a pharmaceutical active substance (page 8, Example 1, ketoprofen), 56% by weight of Eudragit RSPM and 34% by weight of Precirol (page 4, lines 24-27, glycerol palmitostearate which is a species of fatty acid ester denoted in claim 22, line 5) obtained by melt extrusion and cooling to solidification.

The claims are a product-by-process directed to an oral or dermal medicinal composition prepared by melt-mixing the pharmaceutical active substance, acrylic plastic and flow improver. According to *In re Thorpe* (227 USPQ 964, 966, Fed. Cir. 1985) and MPEP §2113 (the section entitled "PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS"), "the patentability of a product does not depend on its method of production.

If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

De Haan et al produces an oral medicinal composition containing a pharmaceutical active substance, acrylic plastic and flow improver within the claims. Although the prior art method of solvent-blending the components differs from the claimed product-by-process wherein the product is obtained by melt-mixing, the claimed product is the same as or obvious from the product of the reference. The burden of proof shifts to appellants to present evidence establishing an unobvious difference between the claimed and prior art products (*In re Marosi*, 218 USPQ 289, 292, Fed. Cir. 1983). The declarations do not confirm an unobvious difference for the reasons epoused in the ***Response to Arguments*** section.

Although the oral medicinal composition of De Haan et al is prepared by solvent-blending, the reference is not limited solely to such a mixing process. It would have been obvious to mix the components of De Haan et al via the melt-blending process of Mueller et al and the European patent in order to eliminate the extra step of introducing a solvent (Mueller et al, col. 3, lines 21-22).

The claimed mixture of acrylic plastic and flow improver as non-homogeneous is not recited. Each of the references exemplifies or discloses a mixture composed of a Eudragit acrylic plastic and cetyl alcohol (De Haan et al), polyethylene glycol (Mueller et al) or glycerol palmitostearate (European patent) which are particular named species within the specification and claim 22. Based on the large disparity in the melting temperature and molecular weight between the Eudragit acrylic plastic, and cetyl alcohol, polyethylene glycol or glycerol palmitostearate of the references, the prior art mixtures inherently display a non-homogeneous morphology.

The claimed thermoplastic coating and binding agent which "consists essentially of" an acrylic plastic and flow improver does not preclude the hydroxyalkylcellulose of Mueller et al since its presence does not materially affect the basic and novel characteristics of the claimed invention (*In re Herz*, 190 USPQ 461, 463, CCPA 1976 and MPEP §2111.03). Included within the context of the "consisting essentially of" parameters are "other additives common in medicine coatings" as revealed on page 15, line 24 to page 16, line 3 of the specification. The common use of hydroxyalkylcellulose in medicine coatings is corroborated by De Haan et al (col. 4, lines 34-35 wherein it is employed in the housing phase). The burden of proof shifts to appellants to demonstrate that the additional hydroxyalkylcellulose would materially change the characteristics of appellants' invention (*In re De Jajarte*, 143 USPQ 256, CCPA 1964). Such a burden has not been met.

(11) Response to Arguments

As explained in the ***Ground of Rejection*** section hereinabove, the claims are directed to a product-by-process of an oral or dermal medicinal composition. De Haan et al shows the solvent-blending of a pharmaceutical active substance, an Eudragit acrylic plastic and cetyl alcohol. The product for both patentees and appellants is a medicine coated and bound by a formulation of an acrylic plastic and cetyl alcohol regardless of the process of preparation. No distinction is seen between the prior art and claimed pharaceutical active substance coated and bound by a combination of acrylic plastic and cetyl alcohol.

Furthermore, the mixing method of De Haan et al is not confined to solvent blending. Column 6, lines 42-49 discloses that the restraining phase particles "can be obtained" by mixing the drug, acrylic plastic and cetyl alcohol with a granulation liquid. There is no requirement that the components can only be blended in the presence of the granulation liquid. It would have been obvious to mix the components of De Haan et al via the melt-blending process of Mueller et al and the European patent in order to eliminate the extra step of introducing a solvent (Mueller et al, col. 3, lines 21-22).

As addressed in the ***Ground of Rejection*** section hereinabove, the claimed thermoplastic coating and binding agent which "consists essentially of" a thermoplastic acrylic plastic and flow improver encompasses "other additives common in medicine coatings (specification, page 15, line 24 to page 16, line 3)" such as the hydroxyalkylcellulose of Mueller et al. The hydroxyalkylcellulose is a common additive to medicine coatings (De Haan et al, col. 4, lines 34-35) which does not materially affect the basic and novel characteristics of the claimed thermoplastic coating and binding agent. There is no evidence addressing the effect of the hydroxyalkylcellulose on the claimed coating and binding agent. The declaration and supplemental declaration is not germane to this issue since it pertains to the criticality of the claimed hot-melt application temperature of from 100-150 °C.

Although the thermoplastic coating and binding agents of Mueller et al and the European patent are not characterized by the claimed "non-homogeneous mixture," the use of Eudragit acrylic plastics, and polyethylene glycol or glycerol palmitostearate specifically named in the specification (page 11, lines 3-8 and page 14, lines 6 and 8-11) and claim 22 as molten mixtures without solvents inherently possess a non-homogeneous morphology.

The European patent describes the function of the lipid excipient such as glycerol palmitostearate for solubilizing or gelling the acrylic plastic (page 4, lines 16-18) and for the preparation of a homogeneous granulate prior to extrusion (page 6, lines 1-5).

The claimed "non-homogeneous mixture" entails the mixing of the flow improver B "in an essentially homogeneous manner with the melt of polymer A [to] improve the flowability of the melt, and can be separated when the melt is cooled and solidified as its own phase (specification, page 11, lines 13-17)." Thus, a clear distinction is made between the morphology in the mixing state (homogeneous) as opposed to that once the melt is solidified (non-homogeneous).

There is no difference between the mixing of the acrylic plastic and glycerol palmitostearate of the European patent and that of the claims since both involve the same components blended to a homogeneous state. The structures of the oral medicinal compositions of the European patent, Mueller et al and the claims are indistinguishable once solidified due to the use of identical or equivalent acrylic plastics and flow improvers which are combined by melt-blending. The solidified oral medicinal compositions of the European patent and Mueller et al are inherently non-homogeneous absent a showing of unexpected results demonstating any structural variations.

Based on the description on page 11, lines 13-19 of the specification, the claimed limitation denoting the thermoplastic coating and binding agent as being a "non-homogeneous mixture" must be interpreted as pertaining to the state of the mixture subsequent to solidification (considering the contradictory disclosure that the components are "mixed in an essentially homogeneous manner").

Therefore, the solidified compositions of the European patent as well as De Haan et al and Mueller et al inherently exhibit the claimed non-homogeneity due to the identical or equivalent acrylic plastics and flow improvers within the claimed realms.

The evidence presented in the declarations filed June 21, 1999 (Paper No. 31) and October 5, 1999 (Paper No. 36) attempts to illuminate the criticality of the claimed application temperature of from 100-150 °C.

The claims necessitate the combination of an acrylic plastic and flow improver as a non-homogeneous mixture. According to the Conclusion on page 2 of both declarations, mixtures embraced by the claims exhibit miscibility in the melt state leading to optical clarity (first declaration) and demonstrate an interaction between the polymer and flow improver. These features are indicative of homogeneity which is contrary to the claimed "non-homogeneous mixture."

Accordingly, the evidence is confusing since the examples allegedly reflective of the claims (supplemental declaration, page 2 Table, the examples at 100 °C and 150 °C) show a greater homogeneity than those at 65 °C, thereby directly contradicting the claimed "non-homogeneous mixture" limitation. In fact the examples at 65 °C more closely exhibit non-homogeneous morphologies due to their characterization as inhomogeneous (first declaration, rating 1) and no polymer-flow improver interaction (supplemental declaration, the symbol "-").

The data provided in the table on page 2 of the first declaration are inconclusive since the examples at 65 °C representative of the closest prior art mixing temperature of the European patent are not compared to examples within the scope of the claimed mixing temperature of from 100 °C to 150 °C. The results for the examples at 65 °C cannot be evaluated since the morphologies for examples within the claimed mixing temperature range are not provided.

The ratings 1-4 are based on visual observations which can vary as a function of the observer. There is no scientific basis for the corroboration of the claimed ratings in the absence of any empirical showings such as microphotographs.

The Table on page 2 of the supplemental declaration is accompanied with microphotographs. If the depiction of a clear interior of a particle surrounded by a black outline indicates the desired polymer-flow improver interaction (which contradicts the claimed non-homogeneous mixture), the sole conclusive difference between the morphology at 65 °C and that at 100 °C and 100 °C is shown for stearyl alcohol. However, the examples at 65 °C are more structurally similar to those at 100 °C than a comparison of the examples at 100 °C and 150 °C. In other words, the examples possessing the claimed mixing temperature of 100 °C are more structurally related to the prior art examples at 65 °C than the examples at the claimed maximum of 150 °C.

Consequently, the actual critical point of polymer-flow improver interaction cannot be ascertained within the claimed mixing temperature range since the morphology at the claimed minimum more closely resembles that of the closest prior art mixing temperature.

The microphotographs reveal structural distinctions between species of flow improver (notice the shape differences between species at 100 °C) and between the same type of flow improver at diverse concentrations (observe the shape variations for examples containing glycerol monostearate, GMS, at 100 °C for proportions of 50% and 80%). Accounting for morphological diversity between species of flow improver and the amount combined with the acrylic plastic, the evidence is not commensurate in scope with the claims regarding a representative sampling of the claimed species of flow improver including such chemically different types as a fatty alcohol, a sugar, a fatty acid triglyceride and a wax. A mere testing at 50% and 80% of flow improver does not confirm the criticality of a level of as low as the claimed minimum of 5% wherein the flow improver could have a negligible effect on the polymer-flow improver interaction.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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PRIMARY EXAMINER
GROUP 150

rs
January 24, 2000

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